

NPPTL NIOSH Respirator Certification Program

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Certification Objective: To establish the performance and quality for NIOSH certified respiratory protective equipment used in the field by validating **design, materials and manufacture**, and **quality assurance** procedures **42 CFR Part 84.1(c)**

FY2010: 186 requests for new approvals, 81 granted; 282 requests for extensions, 209 granted

Initial Administrative Review

- Ensure application is complete

Initial Engineering Review

- Design, Materials, Construction
- Appropriate testing
- Pretest data

Quality Assurance Review

42 CFR Part 84 Subpart E

- Quality Program for Manufacturer of Respirators

- MIL-STD-414, 11 June 1957
Sampling Procedures and Tables for Percent Defective
- MIL-STD-105D, 29 April 1963
Sampling Procedures and Tables for Inspection by Attributes
- Equivalent

Critical: 100% inspection

- Likely hazard to life or health

Major A: AQL ≤ 1.0%

- No respiratory protection
- Undetectable degradation in protection

Major B: AQL ≤ 2.5%

- Detectable degradation in protection

Minor: AQL ≤ 4.0%

- Low impact on protection

AQL: Acceptable Quality Level

Laboratory Testing

- Compliance to standards

Air purifying 58 procedures

Air supplying 54 procedures

Air purifying CBRN conditioning 59 procedures

Air purifying CBRN conditioning 2 procedures

http://www.cdc.gov/niosh/npptl/stps/Respirator_Testing.htm

Final Engineering Review

- Consider quantitative reviews
- Qualitative review

Concurrence

- All elements of approval application evaluation are met.

Approvals

	13F SCBA	14G Gas Masks	19C SAR	21C Particulate	23C Chemical Cartridge	74	84A Particulate Filter
All (manuf.)	659 (30)	224 (15)	404 (38)	736 (41)	2545 (30)	19 (5)	5328 (58)
FY 2010	11 (2)	3 (2)	2 (2)	7 (5)	28 (6)	Obsolete	100 (18)

Stakeholders

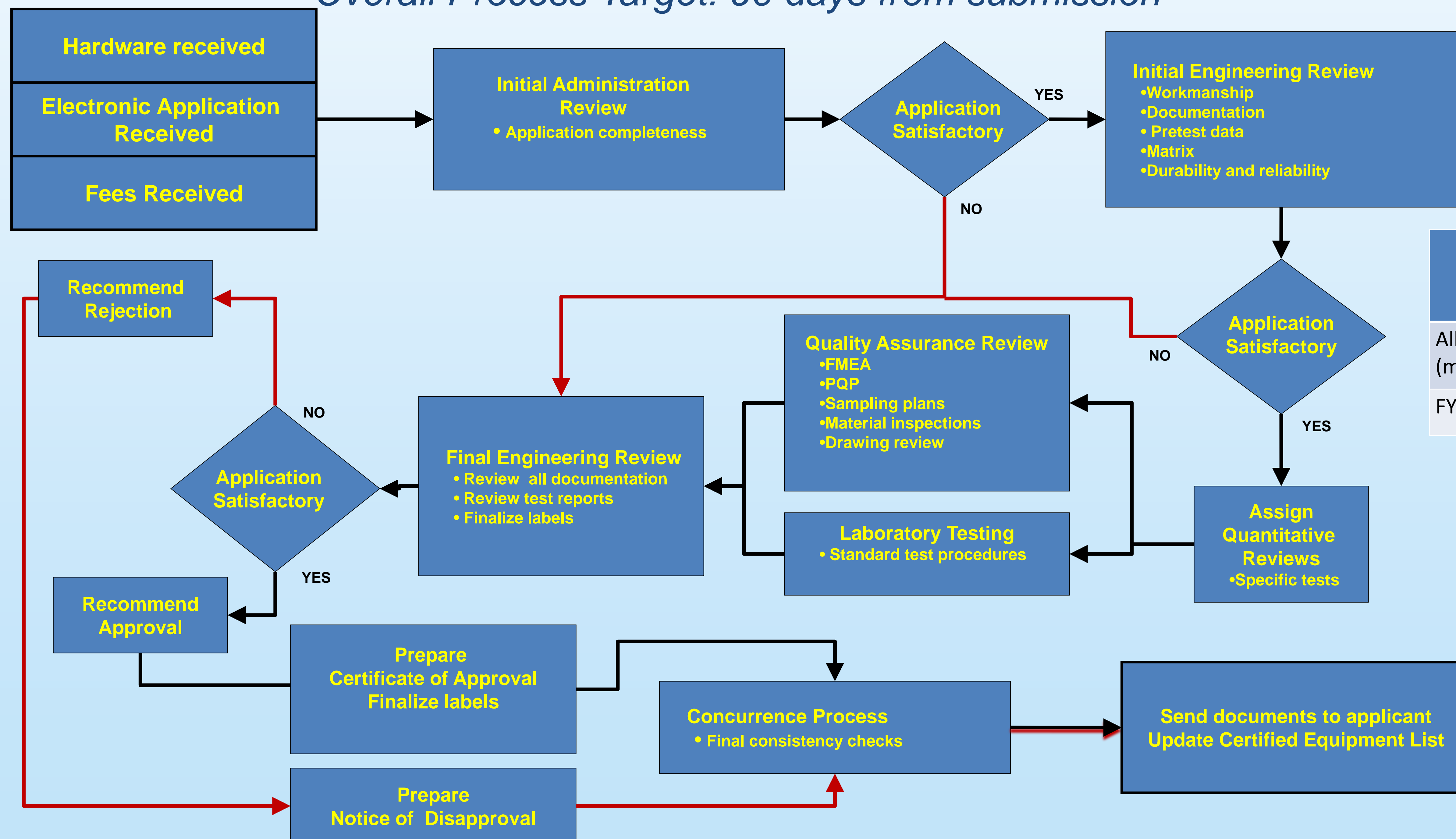
- Respirator Users
- Respirator Manufacturers – worldwide
85 current approval holders
- Other agencies/industrial groups

Outcome

Respirator users are enabled to choose respirator devices appropriate for their needs.

Overview of Approval Process

Overall Process Target: 90 days from submission



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